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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,953	12/10/98	FODSTAD	0 7885.56USWO

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EXAMINER	
SISSON, B	
ART UNIT	PAPER NUMBER
1655	5

DATE MAILED: 12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/125,953	Oystein Fodstad et al.
Examiner	**Group Art Unit**
Bradley L. Sisson	1655

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-11* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2, 3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method of claim 10 is drawn to use of previously unknown genes in gene therapy. The specification does not set forth a repeatable procedure whereby one of skill in the art at the time the subject application was filed, would have been able to have used any unknown gene in a gene therapy method, regardless of it source, *e.g.*, human, non-human animal, plants, etc. At best, the specification suggests that one may, some day, be able to use previously unknown genes, in gene therapy. To require the skilled artisan to identify these unknown genes and to develop the required methods of their use in a gene therapy method places an undue burden on the public/skilled artisan. The situation at hand is analogous to that of *Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001 (CAFC 1997). In *Genentech* the court heard argument that the specification of a patent did not contain sufficient detail concerning the practice of a claimed method (*i.e.*, use cleavable fusion expression to make hGH without undue experimentation); *Ibid*, 1004. As set forth at page 1005:

> Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536. 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....
>
> [2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate written description.

Claim 11, drawn to obtaining specific genes and their expression products from target cells wherein said target cells and the resultant expression products are unlimited, *i.e.*., the target cells and the genes/gene products can be previously unknown. The specification does not set forth a repeatable procedure whereby one of skill in the art would be able to produce the expression product for any gene isolated from any target cell. The specification does not identify the activity of any gene, nor does it set forth a repeatable procedure whereby one of skill in the art would be readily able to ascertain whether any given gene product so produced has the requisite activity. Further, the specification does not set forth a repeatable procedure whereby one of skill in the art at the time the

subject application was filed would have been able to use any product of any said target gene. Like claim 10 *supra*, the specification, at best, only provides a suggestion that gene products produced in accordance to the claimed method may be useful. However, must what these gene products are and how their activity and use is to be ascertained is left for the skilled artisan to determine. Such reliance upon the skilled artisan to provide the novel aspects of the invention is improper. See *Genentech*.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Høifødt et al. (WO 95/24648).

Høifødt et al., disclose a method for identifying genes with site-specific or site preferred expression in specific target cells wherein said target cells are initially detected and isolated by repeated immunomagnetic procedures (page 6, last paragraph, bridging to page 7); wherein the target cells can be malignant cells, including those found in bone marrow, blood, other bodily fluids, tumors, etc. (Page 6 penultimate paragraph); wherein the target cells can be cultured and subjected to further

biochemical analysis, including conducting PCR on cDNA derived from RNA (page 7, bridging to page 8).

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. from 5 p.m. to Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

B. L. Sisson

BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP ~~1800~~ 1650
12/6/99